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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,235	08/21/2003	Mahmoud F. Abdelgany	SPINE 3.0-298 DIV 1	7163
530 7590 06/23/2009 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER SWIGER III, JAMES L				
ART UNIT		PAPER NUMBER		
3775				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/645,235

**Applicant(s)**

ABDELGANY ET AL.

**Examiner**

JAMES L. SWIGER

**Art Unit**

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-7, 11, 14-40 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-7, 43-46 and 48 is/are allowed.
- 6) ☒ Claim(s) 1, 11, 14-29, 36-40, 42 and 47 is/are rejected.
- 7) ☒ Claim(s) 2, 3 and 30-35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/22/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/27/2009 has been entered.

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "42" has been used to designate both a cam member and cutting guide. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

The continuing data needs to be updated at the beginning of the specification, US Pat application 09/742923 is US patent 6,648,894.

The disclosure is objected to because of the following informalities: In Paragraph 0036 applicant has referred to a guide insert as 36b. However this is not shown in the drawing of Fig. 7B as applicant notes in the spec. However applicant has shown in Fig. 7B a guide insert *14b*, so this should be corrected.

The disclosure is objected to because in Fig. 3, of paragraph 0039, there is a "cutting guide insert" without a numerical label. however in paragraph 0035, applicant refers to the cutting guide as 14. As can best be ascertained, the #42 in Fig. 3 should be 14, as would be logical with the objection of 14b in paragraph 0036, how it is still unclear if then the cutting guide of 0035 (#14) is the same as cutting guide insert (presumed replacement for #42, Fig. 3).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim element "means for forming a pattern" and "means for cutting through" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph.

However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

### ***Claim Rejections. 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6-7, 11, 14-29, 36-40, 42, 44-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duvillier et al. (US Patent Number 5,749,876).  
Duvillier et al. disclose various embodiments for manipulating a bone for providing a

bone graft having a desired shape comprising a main body, 14, 21, 24 (block) & 61, with a guide receiving opening, 19, and protrusions, e.g. 16, a holder, 28, an insertable hole guide, 46, containing a plurality of linear hole guides, 49, arranged in a pattern generally corresponding to the desired shape of the bone graft, and an insertable cutting guide, 30, containing slots (it is noted the device shows a side view of slots in Fig. 4), hinged portions at 37 on 24 and 19 on 14 and a clamping mechanism, 61 (see also various embodiments in figures 2 and 3), said body further comprises a mounting structure 61 to facilitate detachably mounting said cutting guide to said body and a securing element 18 to secure said cutting guide to said mounting structure. Regarding claim 11, the body includes a first member, e.g. 21 and a second member, e.g. 24, pivotally connected to one another (see figure 2 and column 7, lines 40-65).

With regards to the limitations requiring the hole pattern "allowing for holes to be made along first and second spaced apart portions of the perimeter of the bone graft," it is noted that hole guide 46 could simply be moved from one portion of the perimeter to the other to allow for holes to be made along the first and second spaced apart portions of the perimeter of the bone graft. Regarding the cutting pattern for "allowing for cuts along at least first and second spaced apart portions of the perimeter of the bone graft," it is noted that the cutting guide 30 could simply be moved from one portion of the perimeter to the other to allow for cuts to be made along the first and second spaced apart portions of the perimeter of the bone graft. Additionally, the language of claims 16 and 25 requiring the plurality of bores be interconnected, and the plurality of bores are

interconnected by virtue of the fact that the bores are all formed in the same plate which interconnects them.

It is noted that the preamble of claims 1, "A bone graft forming guide for providing a bone graft having a desired shape" and the preamble of claims 11, 27 and 42 recites "An instrument for use in forming a bone from bone graft material", both of which amount to an intended use recitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Furthermore, with regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over *Duvillier et al.*, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 45.8, 459 (CCPA 1963). Moreover, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983).

Claim 38 rejected under 35 U.S.C. 103(a) as being unpatentable over *Duvillier et al.* (US Patent Number 5,749,876). *Duvillier et al.* disclose the claimed invention except the outline being arcuate. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device of *Duvillier et al.* having an arcuate outline, since it is just one of numerous shapes or

configurations a person of ordinary skill in the art would find obvious for the purpose of providing various shaped bone grafts. In re Dailey and Eilers, 149 USPQ 47 (1966).

It is further noted that with respect to the various embodiments whether for cutting or forming holes as taught by Duvillier, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Duvillier using any of the varied embodiments since doing so would enable the surgeon to have the tools and options necessary for creating a bone graft as needed with proper shaping.

#### ***Allowable Subject Matter***

Claims 5-7, 43-46, 48 allowed.

Claims 2-3, 30-32, and 33-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments, see response, filed 3/27/2009, with respect to the rejection(s) of claim(s) 1, 6-7, 11, 14-29, 36-40, 42, 44-45, 47 under anticipation under Duvillier have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as unpatentable over Duvillier. Further with regards to claim 11, the cutting and clamping mechanisms are claimed as being only associated with the main body. They do not appear to necessarily be inserted or imported into the main structure.



***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F 9-530.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
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